METHOD AND DEVICE FOR MEASURING FLUCTUATIONS IN THE CROSS-SECTIONAL AREA OF HAIR IN A PRE-DETERMINED SCALP AREA

BACKGROUND OF THE INVENTION

1. Field of the Invention.

The present invention relates to a method and device for measuring fluctuations in the cross sectional area of a bundle of hair for the purpose of documenting the clinical course of medical hair loss disorders and the effectiveness of hair growth treatments and/or for the purpose of indirectly calculating the severity of balding disorders or efficacy of hair growth treatment as evidenced by a decrease or increase in hair population and/or hair shaft diameter.

2. Description of the Related Art.

Heretofore, a hair volume-measuring device used for measure of hair damage was disclosed in the Kabacoff et al. U.S. Patent No. 4,665,741.

Hair shedding is a condition characterized by loss of hairs of normal-sized diameters. It is one of the two major categories of hair loss. Shedding is diffusely distributed over the scalp and may be the sign of several medical abnormalities and toxicities. It may physiologically follow high fever, cessation of birth control pills, or childbirth. Shedding is characterized by the appearance of skin on the scalp where hair was once present. Shedding may be quantified by measuring the density of hairs present in an area of one-centimeter square of scalp. Hair density usually is measured by closely cutting the scalp hair (about 2mm long in an area 5mm X 5mm) and then counting the remaining cut hairs present on the scalp. The hair density of normal individuals in the absence of shedding ranges between 120 to 200 hairs per sq cm of scalp.

Hair thinning is a condition characterized by the gradual miniaturization of individual scalp hairs. It is the second major category of hair loss. The appearance of hair loss is the result of decreasing diameters resulting in the eventual absence of hairs. Thinning (like shedding) also is diagnosed by the appearance of skin on the scalp where hair was once present. Thinning affects an estimated 75% of men and 10% of women. Unlike shedding, it is not diffuse in its distribution over the entire scalp surface, but almost always appears in a pattern, with hair loss on the top of the scalp. Thinning characteristically spares the posterior and sides of the lower scalp, creating a familiar horse-shaped fringe that persists in spite of the most advanced cases.

Thinning occurs in healthy individuals and is referred to as balding, pattern balding, male or female pattern alopecia, androgenctic alopecia, male or female pattern balding. It is considered normal in 75% of men. And, although it may occur in healthy women, it may indicate an endocrine abnormality in a small group of women.

Early pattern balding is difficult to diagnose and difficult to quantify. Simple density measurements (as performed in shedding) are of little value because there is a mixed population of both normal-sized and miniaturized hairs. When density counts are performed, a normal and miniaturized hair would each be counted as one hair. Therefore, in order to detect and quantify thinning in a meaningful manner, the actual hair mass (the collective cross sections of hair from a pre-determined area of scalp) must be measured. This alone would reflect the density of hairs and the array of mixed diameters that are present.

In order to quantify pattern and diffuse hair loss, scientists have commonly used three basic methods:

1. Hair density count
2. Clinical photography
3. Hair weight.

Quantification of hair loss by measuring the collective cross sections in a pre-determined area of scalp has not been reported in the scientific literature nor disclosed in prior U.S. Patents.

The three commonly used methods are described in more detail below:

Density count: The density of an area of scalp is compared to the known normal range of values, which is 120 to 200 hairs per sq cm. To determine the percent loss of density for a single individual, the density on the top part of the scalp (the area of loss) may be compared to the density on the lower back and sides (the normal and permanent hair zone). The percent hair loss is calculated by dividing the hair count in the hair loss area by the hair count in the permanent zone. This method is satisfactory if the condition is one of shedding, but it is quite imprecise in conditions of thinning, because it measures only the number of hairs and makes no allowance for their variations in diameter. The method is used however because it is a bit more precise than clinical photography. It requires cutting off hair and direct scalp exam with a hand lens or video microscope.

Clinical photography: Photography is performed comparing the patient's hair loss area to the permanent zone. It may also compare the patient's hair loss zone to a picture of the same zone of a patient with no hair loss, or of a prior or subsequent state of loss in the same patient. In this manner, the growth or loss is grossly quantified by visual observation alone. No insight is gained into whether or not the hair loss is the result of thinning or shedding. Photography is quite imprecise and obscured by various hairstyles and hair lengths. It is however the most common form of hair loss documentation because it is rapid, requires not special training and is easily archived. It does not require the cutting of hair, but dose require standard photo equipment lighting, positioning of hair and sufficient hair length, to yield any kind of comparable data.

Hair weight: A small area of hair (usually 5mm x 5mm) is shaved from a balding area. The patient returns in 30 days and the newly grown hair is cut and weighed. The value is compared to a subsequent similar assay of the same area. In cases of pattern loss, the procedure may be performed in the permanent zone (lower posterior and lateral horseshoe shaped zone) and compared to the value in the thinning zone. The percent hair loss may be calculated by dividing the hair weight in the thinning area by the hair weight in the permanent zone. Hair weight is a very precise method of measuring hair loss because it considers both the number of hairs and their diameters and the hair length in its calculation. Its disadvantage is that the sample size represents a very small portion of the scalp surface, and may in fact may not be as precise as thought.

Furthermore it is a very tedious process and impractical to perform in a clinical setting. It also requires cutting off hair. It is used primarily by commercial laboratories to measure the effectiveness of hair-growing preparations i.e. finasteride, dutasteride, etc.

BRIEF SUMMARY OF THE INVENTION

According to the present invention there is provided a method and device for measuring fluctuations in the cross sectional area of a section of hair as it relates to the quantification and clinical course of medical hair loss disorders or the effectiveness or progress of hair loss treatment. The method and device are used for determining the cumulative cross-section of hairs within a pre-measured area. The method and device uses a much larger sample of scalp surface than the hair

weight method and hair cutting is not required. The length of the hair is not considered a factor in the evaluation because of the wide variations of individual styling would make it impossible, or clinically relevant. The method of the present invention is easy to perform in a non-laboratory setting and employs a new hand-held device. The method and device allow physicians and hair care professionals to track and document the status of patients, suffering from scalp hair thinning or shedding, at any time in the course of their evaluation or treatment. The method and device may be used to quantitatively evaluate the effectiveness of hair growing preparations and drugs and quantify the severity and clinical course of other medical hair loss disorders.

In practicing the method of the present invention, a predetermined area of hair-bearing skin or scalp is isolated by any of several means. Typically a 2 x 2 cm of scalp hair is manually isolated using a comb or combing element and fixed in place using 1 x 3" gummed papers printed with a centimeter scale which are aligned and overlapped in the configuration of a 2 x 2 cm square. Alternatively, a 2 x 2 cm area may be isolated by using any device that demarcates the periphery of the area, such as with a ruler and washable ink, marking pen, and/or using a simple comb-like device that is 2 cm. in length, which simultaneously bundles the hair and demarcates the perimeter of the area.

The bundle is snared by a spring-loaded hook-like ("J" shaped) arm which is drawn into a body of the device of the present invention. The device comprises a hair-trapping element including a "J" shaped end that extends through a boss and has a hair-receiving slot. The device further includes an anvil on an end surface of the boss positioned adjacent the slot whereby relative movement between the "J" shaped end and the anvil compresses the hair received in the slot. A compression spring is provided in the device which bears against the boss. Alternatively the device can have an anvil that moves into a stationary slot.

The bundle is captured in the slot and automatically immobilized against the anvil on the boss. Preferably, the slot is 1mm wide and 12mm high and relative movement between the anvil and the slot measures the height of the hair. In this manner, the load on the column of trapped hair may be precisely measured and thereby kept constant in repeated measurements. This is important because the hair bundle is quite compressible. The mm height of the hair column is displayed on an LED window of an integrated micrometer head that causes relative

movement between the anvil and the slot. If a mechanical load gage is incorporated in the design of the device, it is displayed on the face of an analog dial. If an electronic load cell is incorporated into the device, the load is displayed on an LED window. The height of hair in the trapping hair-receiving slot is expressed as an arbitrary value that shall be called the hair mass, the hair mass index, the cross-sectional index, the cumulative cross-sectional index, or the combined cross-sectional index.

The method is performed in the hair thinning area and the permanent hair growth area of the scalp. The index value of the thinning area is divided by the index value of the permanent area. The percent loss of hair mass in the thinning area is thus derived. It is believed that the method and device of the present invention may have profound medical significance for the following reason: It is a known medical fact that an individual must lose half of the hair in an area of the scalp, before it is obvious to the casual observer that any hair has been lost. This can also be demonstrated by the casual observers inability to tell the difference between a toupee with 200 hairs per sq cm and a toupee with 100 hairs per sq cm. This observation however translates to the following: By the time an individual realizes that he is "losing hair" he has already lost half of his hair! The device of the present invention enables hair professionals and physicians to measure the hair mass in the pre-balding normal-looking areas of the scalp and compare these values to the hair mass value in the permanent zone. In this way one can detect whether or no t there is hair loss years before it is visually obvious to the patient or his physician. The patient is alerted to the early hair loss and may enjoy the advantages of starting therapy before the loss has significantly advanced. The method and device may also be used to track and quantify the progressive hair loss of individuals with untreated balding, or track and quantify the therapeutic response of hair to drugs and devices that allegedly grow hair.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 is a top view of a scalp showing a section or bundle of hair that is combed from a delineated section of scalp with a combing element and shows one side of the section of scalp being delineated by a gummed label.

FIG. 2 is a top view of a scalp showing a section or bundle of hair that is combed from a delineated section of scalp and shows two sides of the section of scalp being delineated by gummed labels.

FIG. 3 is a top view of a scalp showing a section or bundle of hair that is combed from a delineated section of scalp and shows three sides of the section of scalp being delineated by gummed labels.

FIG. 4 is a top view of a scalp showing a section or bundle of hair that is combed from a delineated section of scalp and shows four sides of the section of scalp being delineated by gummed labels.

FIG. 5 is a plan view of one combing element.

FIG. 6 is a top plan view of the scalp shown in FIG. 4 and a device constructed according to the teachings of the present invention for measuring the cross-sectional area of the bundle of hair.

FIG. 7 is a top plan view of a scalp shown in FIG. 6 with a "J" shaped end of the device move toward a boss on the body of the device to measure the cross-sectional area of the bundle of hair positioned in a slot of the "J" shaped end.

FIG. 8 is a fragmentary enlarged view of the hair trapped in the slot of the "J" shaped end.

FIG. 9 is a cross-sectional view of the "J" shaped end taken along line 9-9 of FIG. 8.

FIG. 10 is a cross-sectional view of a boss extending from the body of the device and in which the "J" shaped end is received.

FIG. 11 is a plan view of the device without a bundle of hair in the slot of the "J" shaped end, shows the "J" shaped end moved over the boss, and is broken away to show a heavy compression spring In the body of the device.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIG. 1 there is illustrated therein a combed bundle or section of hair 10 from a scalp 12, that has been combed with a comb or combing element 14. The bundle 10 of hair is delineated from a predetermined area of the scalp 12 by a gummed label 16, without cutting the bundle 10 of hair.

As shown in FIG's. 2-4, sequentially the delineated area of the scalp is fixed by gummed labels 18, 20 and 22. Each gummed label has a centimeter

scale printed thereon so that the predetermined area, e.g., 2 square centimeters, can be measured and segregated by the gummed labels 16, 18, 20 and 22 from the rest of the hair on the scalp. The gummed labels 16, 18, 20 and 22 are printed with pairs of color-coded lines at intervals 2cm and 1.44cm apart scale. The color-coded lines are aligned and overlapped in a 4 step sequential fashion to create an isolated field of uncut hair that is either 1 or 2cm square.

Preferably, a 2 x 2 cm (or 1 x 1 cm) of scalp hair is manually isolated by combing the hair away from the designated square of hair-bearing scalp skin. This is done in a sequential fashion as described above. Care is taken to maintain a straight line at 90 degrees from the previous passage of the combing element 14.

The combing element 14 is shown in FIG. 5 and has a predetermined tine area 26, e.g., 2 cm. long, with tines 28 and an upwardly sloping top edge 29 extending to a handle 30.

A device 32 is provided, as shown in FIG. 6 for measuring the mass of hair in a bundle 10 from the 2 sq cm area of a hair bearing skin or scalp and compares that hair mass to the hair mass per sq. cm. in a permanent (normal) zone on the scalp.

The device 32 is an electronic caliper 34 having a body 36 with an electronic display 38 and a scale, gauge or analog display 40 for indicating the height or mass of hair in the hair bundle 10.

The device 32 includes a piston or plunger 42 that extends through the body 36 and has a collar 43 thereon below a knob 44 at an outer end 46 of the plunger 42. A return spring 48 (FIG. 7) bears against the collar 43 to urge the knob 44 away from an upper end 49 of the body 36 to push the plunger 42 upwardly. As shown a collar 50 between the spring 48 and the upper end 49 of the body of the body 36 is provided and has a reduced in diameter portion 51 that extends into the body 36.

It will be understood that the scale, gauge or analog display 40 moves with the plunger 42. Also, of course, the amount of movement of the plunger will be shown on the display 38.

The other end 52 of the plunger 42 has a "J" shape defined by a main leg 53 and a hook leg 54 with a slot 56 therebetween. The slot 56 can be 1mm wide and 12mm high or 1.25 mm wide x 12mm high.

The main leg 52 extends through a through bore 58 (FIG. 9) in a boss 60 at a lower end 61 of the body 36.

As shown in FIG. 11 a compression spring 62 in the body 36 bears against a lower end 63 of the reduced in diameter portion 51 of the collar 50.

A wall 64 of the boss 60 between the bore 58 and an outer surface 63 of the boss 60 is slidably received in the slot 56 upon relative movement between the boss 60 and the "J" shaped end 52.

The bundle of hair 10 is placed in the slot 56 and the knob 44 is screwed down on the plunger 42 and moves the reduced in diameter portion 51 of the collar 50 into the body 36 to compress the bundle of hair 10 between a bottom 66 of the slot 56 and an end surface 68 of the wall 54 (FIG. 9) with a predetermined compression established by the spring constant of the heavy spring 62 acting on the plunger 42. The end surface 68 defines an anvil 68 against which the bundle 10 of hair is compressed. In this way the device 32 defines a measuring device comprising the hair-holding slot 56, the "J" shaped end of the spring-loaded plunger 42 and the anvil 68.

The bundle or column 10 of hair is placed into the slot 66 and compressed against the anvil 68 in order to measure its height of the column or bundle 10 of hair. The anvil 68 and plunger are designed in a manner that always applies the same pressure to the column or bundle 10 of trapped hair. (This is accomplished with the compression spring 62 bearing against the reduced in diameter portion of the collar 51) This is important because the hair bundle 10 is quite compressible. The mm height of the hair bundle or column 10 is read off a window on the electronic display 38 and/or off of the scale gauge or analog display 40. This arbitrary value shall be called the hair loss index or the density-diameter index. The procedure is performed in the balding area and the permanent area. The value for the balding area is divided by the value for the permanent area. The percent loss of hair mass in the balding is thus derived.

Oddly, in pattern balding (Androgenetic alopecia), the back and sides of the scalp are immune to the miniaturization process which doctors call miniaturization. So that on a balding scalp, the permanent horseshoe shaped fringe is populated with normal sized hairs (70 microns) with a normal density of 120 - 200 hairs per square cm. On the top of the scalp, in the areas of hair

loss, the population of hairs ranges in size from 70 microns to 15 microns in diameter with a wide range of hairs per square cm.

The cumulative number of hairs per sq cm of scalp times their cumulative diameters equals a value that is best described as the hair mass. When the hair mass value of the balding zone is divided by the hair mass value of the normal permanent zone, the percent loss of hair mass in the balding area is derived. When the hair mass value in an area of loss is compared with a subsequent measurement of the same area at a time in the future, the percent hair loss or growth may be derived.

This information is very important to those who care for patients with hair loss, and those who develop drugs or devices that promote hair growth. Again it must be emphasized that although the length of the hair does contribute to the total visual mass of hair, it is not considered because it varies with cut length of the hair (styling) which has no relevance to intended application of this patent.

From the foregoing description, it will be understood that the method and device of the present invention have a number of advantages, some of which have been described above and others of which are inherent in the method and device of the present invention.

Also modifications can be made to the method and device of the present invention without departing from the teachings of the present invention.

For example, a mark can be placed on the body 36 and another mark placed on the plunger 42 and a separate caliper can be used to measure the distance between the marks for determining the height of hair compressed in the slot 56.

The heavy spring 62 can be omitted and the knob 44 can be tightened with a torque wrench to place a predetermined amount of compression on the bundle 10 of hair.

A simple protrusion with an anvil at the end can used in place of the boss 60 and received in the slot 56.

A simpler device can be provided including a body with the slot 56 therein and a piston having the anvil 68 at one end can be provided and positioned to be received in the slot 56. The body can be moved against the piston or the piston can be moved in and out of the slot 56.

The body and piston can be provided with a return spring, like spring 48, for holding the anvil 68 in the slot 56 until the spring is compressed to move the anvil 68 out of the slot 56.

If desired, side arms can be provided on the body, much like on a syringe, to facilitate gripping of the body while the piston or plunger is reciprocated or the knob 44 is rotated.

The non-isolated hair can be held down by other means, such as a ruler or hair clips instead of with gummed labels.

Further, the caliper can be mechanical or electrical, can be attached to the body or plunger or can be separate from the device 32.

Accordingly, the scope of the invention is only to be limited as necessitated by the accompanying claims.